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SOUTHERN DISTRICT OF CALIFORNIA

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BY:

DEPUTY

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

No.

'99CV 2668H AJB

COMPLAINT FOR DECLARATORY RELIEF

DEMAND FOR JURY TRIAL

PLAINTIFF GEN-PROBE ALLEGES:

INTRODUCTION

1. This action concerns the invalidity and non-infringement of United States Patent No. 5,750,338 ("the '338 patent"). As set forth below, plaintiff Gen-Probe Incorporated ("Gen-Probe") asks this court to declare the '338 patent invalid and further to declare that Gen-Probe's current and anticipated activities do not infringe any valid claim of the '338 patent.

THE PARTIES

2. Gen-Probe was founded in San Diego in 1984 as a small "start up" company, seeking to develop products based on the discoveries of a local research scientist. Over time, Gen-Probe became one of the largest biotechnology firms in San Diego. Gen-Probe now maintains its

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1 principal offices and research facilities at 10210 Genetic Center Drive in San Diego, where it
2 employs over 500 scientists and staff. Gen-Probe is organized under the laws of the State of
3 Delaware.

4 3. Gen-Probe is informed and believes that defendant Vysis, Inc. (hereinafter "Vysis"
5 or "the defendant") is a corporation organized and incorporated under the laws of the State of
6 Delaware. Gen-Probe is further informed and believes that Vysis maintains its principal place of
7 business in Downers Grove, Illinois and that it is controlled by BP Amoco, Inc.

8 JURISDICTION AND VENUE

9 4. Counts One and Two of this Complaint seek declaratory relief under the
10 Declaratory Judgment Act, Title 28, United States Code, Sections 2201 and 2202. This Court has
11 subject matter jurisdiction of the claims asserted thereunder by reason of Title 28, United States
12 Code, Sections 1331 and 1338(a).

13 5. Venue is proper in this District under Title 28, United States Code, Sections
14 1391(a), 1391(b) and 1400(b).

15 BACKGROUND

16 6. Living cells store genetic information in molecules of nucleic acid known as DNA.
17 These molecules consist of long, thin, chain-like strands which, in turn, are usually found in the
18 form of two tightly bound, complementary chains. DNA molecules retain their genetic information
19 in the form of a genetic code. The information in the DNA determines the life processes of each
20 organism. The information in the DNA is used to make related nucleic acid molecules called RNA
21 that cells use to manufacture proteins.

22 7. Through the work of its scientists and staff, Gen-Probe has developed and continues
23 to develop diagnostic tests that seek out the DNA or RNA of the infectious organisms. These types
24 of tests are generally referred to as "genetic probes" or "nucleic acid tests" ("NAT"). Gen-Probe
25 now markets DNA probe products that test for a wide range of microorganisms that cause
26 tuberculosis, strep throat, pneumonia, fungal infections and sexually transmitted diseases. Through
27 the efforts of its scientists and staff, Gen-Probe has emerged as the recognized world leader in the
28 development, manufacture and commercialization of diagnostic products based on its patented

1 genetic probe technology. Gen-Probe has received over 40 FDA clearances and approvals for
2 genetic probe tests to detect a wide range of microorganisms, including Chlamydia, Mycobacterium
3 tuberculosis and Neisseria gonorrhoeae.

4 8. Many human diseases are caused by bacterial or viral agents that invade living
5 cells. Historically, the presence of these bacterial or viral agents was detected directly by time-
6 consuming methods such as culture or indirectly through the detection of antibodies.
7 Unfortunately, it takes time, sometimes weeks or months, to grow organisms in culture, and it
8 usually takes months for the body to manufacture antibodies in sufficient amounts to reveal the
9 presence of infectious agents. Consequently, these methods do not lend themselves to early
10 detection of infection. NAT addresses this problem.

11 9. Among the disease detection technologies recently applied by Gen-Probe is its
12 patented nucleic acid technology known as "Transcription-Mediated Amplification" ("TMA"). This
13 technology enables Gen-Probe's NAT products to detect extraordinarily small quantities of the
14 nucleic acids of infectious agents.

15 10. In September 1996, Gen-Probe received a \$7.7 million grant from the National
16 Institutes of Health to develop TMA-based nucleic acid tests to be used in screening donated blood
17 for and human immunodeficiency virus (HIV), the causative agent of AIDS, and hepatitis C virus
18 (HCV), which causes a severe form of hepatitis.

19 11. At the time of the NIH grant to Gen-Probe, donated blood was principally tested by
20 procedures that detected the presence of antibodies to the viruses being screened. Due to the time it
21 takes for the body to make antibodies after initial infection, donated blood may test negative for
22 antibodies, yet still carry infectious viruses. This delay between the time of actual infection and the
23 time that antibodies can first be detected is often known as the "window period." Reduction of this
24 "window period" was a significant concern of the United States government and the primary focus
25 of the grant to Gen-Probe to develop NAT diagnostics for use in blood screening.

26 12. In fulfilling its obligations under the grant, Gen-Probe developed NAT tests to
27 detect the DNA of HIV and hepatitis C in blood. Through the use of its NAT test, Gen-Probe
28 believes that researchers and medical personnel may rapidly and *directly* detect the presence of

1 genetic material of viruses like HIV and HCV more accurately and without the complications and
2 delay associated with conventional *indirect* tests. As such, Gen-Probe believes that its new test
3 may significantly reduce the "window period" for detection of these extremely harmful viral agents
4 and resulting diseases.

5 13. Final development of the NAT tests for blood screening in the United States is now
6 taking place in testing conducted by the American Red Cross, America's Blood Centers, and others.
7 ("A Purity Quest; Local Biotech's Ultra-Sensitive Blood Screening Could Cut Risk of AIDS,
8 Hepatitis," *San Diego Union*, March 25, 1999, page C-1.) Use of the tests in the United States is
9 made pursuant to an Investigational New Drug Application filed with the United States Food and
10 Drug Administration. In blood tested by the American Red Cross, Gen-Probe's products have
11 detected hepatitis C and HIV which escaped detection by prior methods. ("New Blood Screening
12 Finds Virus Others Missed; Experimental Test Turns Up Hepatitis C In Donated Blood," *San Diego*
13 *Union*, April 2, 1999, page B-2.)

14 14. On September 21, 1999, the French Ministry of Health approved the sale of the
15 Gen-Probe blood screening tests in France. Gen-Probe anticipates approval of its tests for us in
16 Australia in early 2000.

17 15. Gen-Probe has entered into an agreement with Chiron Corporation ("Chiron") of
18 Emeryville, California, with respect to the development, manufacture, and distribution of blood
19 screening products. Gen-Probe is also a party to an agreement with Bayer Corporation ("Bayer") of
20 Emeryville, California with respect to the development, manufacture, and distribution of clinical
21 diagnostic products for the detection of HIV and hepatitis C, among other pathogens.

22 16. Gen-Probe anticipates that clinical trials in the United States of its HIV/HCV tests
23 for use in blood screening and in clinical diagnostics will commence in the first part of 2000. Gen-
24 Probe anticipates the conclusion of those clinical trials, and the initiation of commercial sales in the
25 United States of kits containing its HIV/HCV blood screening test, during 2000.

26 17. All of the Gen-Probe products are manufactured in San Diego, California.

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THE '338 PATENT

18. Gen-Probe is informed and believes that on or about May 12, 1998, the United States Patent and Trademark Office issued United States Patent No. 5,750,338 ("the '338 patent") based upon Patent Application No. 238,080 filed on May 3, 1994.

19. Gen-Probe is informed and believes that defendant Vysis claims to be the owner, by assignment, of the entire right, title and interest of the '338 patent. The claims of the '338 patent purport to relate to assays and probes for polynucleotide molecules such as DNA and RNA.

20. In early 1999, Vysis informed Gen-Probe that it believed that the '338 patent applied to Gen-Probe's NAT blood screening tests for HIV and HCV. Following further discussions and to avoid any complications in Gen-Probe's plans for commercial deployment of its NAT test kits, as of June 22, 1999 Gen-Probe obtained a license from Vysis under the '338 patent. Gen-Probe also obtained options to licenses for its relationships with Chiron and Bayer. Under the terms of the licenses, Vysis requires Gen-Probe (and its allied parties if the options are exercised) to make significant financial payments to Vysis as royalties on the sale of any product covered by valid claims of the '338 patent.

21. Notwithstanding the existence of the licenses, and as further alleged herein, Gen-Probe believes that the '338 patent is invalid in all material respects. Furthermore, Gen-Probe believes that its NAT blood screening tests do not infringe any valid claim of the '338 patent. As such, Gen-Probe disagrees with Vysis' contention that the claims of the '338 patent "apply" to Gen-Probe's activities.

22. Gen-Probe is informed and believes that the defendant disputes and disagrees with Gen-Probe's contentions concerning the non-infringing nature of its present and planned activities and products and the invalidity of the '338 patent, as expressed above and detailed in the following paragraphs of the complaint. Furthermore, based upon a long history of litigation between Gen-Probe and Vysis' and its affiliates, Gen-Probe reasonably anticipates that should it fail to pay royalties pursuant to the Vysis license, Vysis will aggressively attempt to enforce its perceived rights under the '338 patent by terminating the license and through litigation against Gen-Probe, its allied parties, and customers.

1 c. From instituting or prosecuting any lawsuit or proceeding, placing in issue
2 the right of Gen-Probe, its allied parties, distributors, customers, licensees, successors or assigns,
3 and others to make, use or sell Gen-Probe's products.

4 3. For recovery of Gen-Probe's attorneys' fees and costs of suit incurred herein; and

5 4. For such other and further relief as the Court may deem just and proper.

6 Dated: December 21, 1999

7 COOLEY GODWARD LLP
8 STEPHEN P. SWINTON (106398)
9 JAMES DONATO (146140)

10 By: Patrick Maloney for Steve Swinton
11 Stephen P. Swinton

12 Attorneys for Plaintiff
13 Gen-Probe Incorporated
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DEMAND FOR TRIAL BY JURY

Gen-Probe demands trial by jury for all applicable issues arising in connection with its complaint.

Dated: December 21, 1999

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